

PHA-00373.US1
Serial No.: 10/658,164
Preliminary Amendment

Listing of Claims

1. (Amended) Method of determining the dissolution rate of an analyte in a non-aqueous liquid composition, comprising the steps of:
 - 5 (a) providing a non-aqueous liquid composition comprising an analyte and a non-aqueous base;
 - (b) adding a non-aqueous diluent to the non-aqueous liquid composition to provide a diluted non-aqueous liquid composition, wherein the non-aqueous diluent optionally contains at least one surfactant;
 - 10 (c) introducing at least part of the diluted non-aqueous liquid composition and an aqueous dissolution medium into a dissolution testing apparatus, wherein the aqueous dissolution medium comprises a buffer having a molarity of from about 0.1 mM to about 10 mM;
 - (d) contacting the diluted non-aqueous liquid composition and the aqueous dissolution medium for a predetermined time; and
 - 15 (e) determining the amount of analyte in the aqueous dissolution medium, optionally first filtering the sample taken from the aqueous dissolution medium before said determination.
2. (Original) The method of claim 1, wherein the amount of analyte in the aqueous dissolution medium is determined at several different predetermined times.
- 20 3. (Cancel)
4. (Cancel)
5. (Original) The method of claim 1, wherein the non-aqueous liquid composition is a pharmaceutical composition.
6. (Original) The method of claim 5, wherein the analyte is the pharmaceutically
25 active component.
7. (Original) The method of claim 5, wherein the pharmaceutical composition is a sustained release dosage form.
8. (Original) The method of claim 5, wherein the pharmaceutical composition
30 further contains pharmaceutically acceptable components selected from the group consisting of excipients, additives, suspending agents, preservatives, wetting agents,

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thickeners, buffers, flocculating agents, flavoring agents, sweeteners, colorants and fragrances.

9. (Original) The method of claim 1, wherein the analyte is selected from the group consisting of ACE inhibitor; α -adrenergic agonist; β -adrenergic agonist; α -adrenergic blocker; β -adrenergic blocker; alcohol deterrent; aldose reductase inhibitor; aldosterone antagonist; amino acid; anabolic; analgesic; anesthetic; anorexic; antacid; anthelmintic; antiacne agent; antiallergic; antiandrogen; antianginal agent; antianxiety agent; antiarrhythmic; antiasthmatic; antibacterial agent; antialopecia and antibaldness agent; antiamebic; antibody; anticholinergic drug; anticoagulant; blood thinner; anticolitis drug; anticonvulsant; anticystitis drug; antidepressant; antidiabetic agent; antidiarrheal; antidiuretic; antidote; antiemetic; antiestrogen; antifatulent; antifungal agent; antigen; antiglaucoma agent; antihistaminic; antihyperactive; antihyperlipoproteinemic; antihypertensive; antihyperthyroid agent; antihypotensive; antihypothyroid agent; anti-infective; anti-inflammatory agent; antimalarial agent; antimigraine agent; antineoplastic; antiobesity agent; antiparkinsonian agent; antidyskinetics; antipneumonia agent; antiprotozoal agent; antipruritic; antipsoriatic; antipsychotic; antipyretic; antirheumatic; antisecretory agent; anti-shock agent; antispasmodic; antithrombotic; antitumor agent; antitussive; antiulcerative; antiviral agent; anxiolytic; bactericidin; bone densifier; bronchodilator; calcium channel blocker; carbonic anhydrase inhibitor; cardiotonic; heart stimulant; chemotherapeutic; choleretic; cholinergic; CNS stimulant; coagulant; contraceptive; cystic fibrosis drug; decongestant; diuretic; dopamine receptor agonist; dopamine receptor antagonist; enzyme; estrogen; expectorant; glucocorticoid; hemostatics; HMG CoA reductase inhibitor; hypnotic; immunomodulator; immunosuppressant; laxative; miotic; monoamine oxidase inhibitor; mucolytic; muscle relaxant; mydriatic; narcotic antagonist; NMDA receptor antagonist; oligonucleotide; ophthalmic drug; oxytocic; peptide; proteins; polysaccharide; progestogen; prostaglandin; protease inhibitor; respiratory stimulant; sedative; serotonin uptake inhibitor; sex hormone; smoking cessation drug; smooth muscle relaxant; smooth

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muscle stimulant; thrombolytic; tranquilizer; urinary acidifier; vasodilators; and vasoprotectant.

10. (Original) The method of claim 1, wherein the analyte is a cephalosporin selected from the group consisting of ceftiofur, cefepime, cefixime, cefoperazone, cefotaxime, cefpodoxime, ceftazidime, ceftizoxime, ceftriaxone, moxalactam, pharmaceutically acceptable salts and derivatives thereof.
11. (Original) The method of claim 10, wherein the analyte is ceftiofur, a pharmaceutically acceptable salt or derivative thereof.
12. (Cancel)
- 10 13. (Amended) The method of claim 1[[2]], wherein the non-aqueous base is a fat that is an oil.
14. (Original) The method of claim 13, wherein the oil is selected from the group consisting of canola oil, coconut oil, corn oil, peanut oil, sesame oil, olive oil, palm oil, safflower oil, soybean oil, cottonseed oil, rapeseed oil, sunflower oil and mixtures thereof.
- 15 15. (Amended) The method of claim [[12]]14, wherein the oil is selected from the group consisting of cottonseed oil, coconut oil, and combinations thereof, wherein the oil is optionally modified or hydrogenated.
16. (Original) The method of claim 1, wherein the non-aqueous liquid composition is a suspension, solution or emulsion.
- 20 17. (Original) The method of claim 1, wherein the non-aqueous liquid composition is a suspension.
18. (Cancel)
19. (Amended) The method of claim 1[[8]], wherein the non-aqueous diluent is an oil.
- 25 20. (Amended) The method of claim 19, wherein the oil is hydrogenated coconut oil or modified cottonseed oil.
21. (Amended) The method of claim 1, wherein the amount ratio of the non-aqueous diluent to the non-aqueous liquid composition is from 1:20 to 20:1 by volume is from about 0.25 to about 10 parts by weight relative to the amount of non-aqueous liquid composition.
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22. (Original) The method of claim 1, wherein the contacting is conducted for a predetermined time to dissolve from about 10% to about 100% of the total amount of analyte, which was initially present in the non-aqueous liquid composition, in the aqueous dissolution medium.
- 5 23. (Original) The method of claim 22, wherein the stirring is conducted for a predetermined time to dissolve from about 10% to about 100% of the total amount of analyte, which was initially present in the non-aqueous liquid composition, in the aqueous dissolution medium.
24. (Original) The method of claim 1, wherein the aqueous dissolution medium is prepared using high purity water.
- 10 25. (Cancel).
26. (Cancel)
27. (Amended) The method of claim [[26]]1, wherein the buffer solution is selected from the group consisting of glycine buffer at pH ranging from 2 to 3, citrate buffer at pH 3, acetate buffer at pH ranging from 4 to 5, acetate buffer in normal saline at pH 15 5.5, phosphate buffer at pH ranging from 6 to 8, potassium free phosphate buffer at pH 6.8, phosphate buffer in normal saline at pH 7.4, and borate buffer at pH ranging from 8 to 10.
28. (Cancel)
- 20 29. (Amended) The method of claim 27, wherein the buffer is the phosphate buffer at pH ranging from 6 to 7 ~~has a molarity of from about 1 mM to about 5 mM.~~
30. (Amended) The method of claim 1, wherein ~~in step (d)~~ the ratio of non-aqueous liquid composition to aqueous dissolution medium is from about 1 : 2,000 to about 1 : 100,000 by volume.
- 25 31. (Amended) The method of claim 30, wherein ~~in step (d)~~ the ratio of the diluted non-aqueous liquid composition to the aqueous dissolution medium is from about 1 : 5,000 to about 1 : 40,000 by volume.
32. (Original) The method of claim 1, wherein the dissolution testing apparatus is a paddle assembly.
- 30 33. (Cancel)

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34. (Cancel)
35. (New) Method of determining the dissolution rate of an analyte in a non-aqueous liquid composition, comprising the steps of:
- 5 (a) providing a non-aqueous liquid composition comprising an analyte and a non-aqueous base;
- (b) adding a non-aqueous diluent to the non-aqueous liquid composition to provide a diluted non-aqueous liquid composition, wherein the ratio of the non-aqueous diluent to the non-aqueous liquid composition is from 1:20 to 20:1 by volume, and wherein the non-aqueous diluent optionally contains at
- 10 least one surfactant;
- (c) introducing at least part of the diluted non-aqueous liquid composition and an aqueous dissolution medium into a dissolution testing apparatus, wherein the ratio of non-aqueous liquid composition to aqueous dissolution medium is from about 1 : 2,000 to about 1 : 100,000 by volume, and wherein the
- 15 aqueous dissolution medium comprises a buffer having a molarity of from about 0.1 mM to about 10 mM;
- (d) contacting the diluted non-aqueous liquid composition and the aqueous dissolution medium for a predetermined time; and
- (e) determining the amount of analyte in the aqueous dissolution medium,
- 20 optionally first filtering the sample taken from the aqueous dissolution medium before said determination.
36. (New) The method of claim 35, wherein the analyte is ceftiofur crystalline free acid, wherein the non-aqueous base is a combination of modified cottonseed oil and hydrogenated coconut oil, wherein the non-aqueous diluent is hydrogenated
- 25 coconut oil, and wherein the aqueous dissolution medium is a phosphate buffer having a molarity of 1mM and a pH of 7.